ARC 2929C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136A.8, the Iowa Department of Public Health hereby amends Chapter 4, "Center for Congenital and Inherited Disorders," Iowa Administrative Code.

These amendments rescind the requirement of the Department to establish policies and procedures, including obtaining an informed consent for the release of residual newborn screening specimens for research, that would allow a parent or guardian the ability to provide informed consent prior to the release of a newborn's residual newborn screening specimen for research purposes. The Department director has accepted a recommendation from the Congenital and Inherited Disorders Advisory Committee (CIDAC) to discontinue releasing specimens for external research use without informed consent and makes it the responsibility of the investigator of the proposed research to obtain informed consent from the parent or guardian for the release of the newborn's specimen. Amendments to related subparagraphs support this change in policy.

These amendments will allow reporting requirements for newborn critical congenital heart disease (CCHD) screening to reflect the implementation of the Iowa Newborn Screening Information System (INSIS), thereby enabling newborn care providers to enter CCHD screening results. A portion of the fees from the Iowa Newborn Screening Program (INSP) and the Iowa Maternal Prenatal Screening Program (IMPSP) are currently distributed to the Department to support a percent of effort of the executive officer of the Center for Congenital and Inherited Disorders (CCID). These amendments will allow program fees distributed to the Department to be used for INSP and IMPSP activities.

The amendment in Item 9 corrects a typographical error.

These amendments have been reviewed by CIDAC and interested individuals within the field.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2819C** on November 23, 2016. Public comments were received from the Midwest Region of the March of Dimes in support of the proposed amendments. The public comments from the Midwest Region of the March of Dimes are summarized as, "Of particular note in the proposed regulation is the research and parental consent provision, which comports with our position."

To clarify the intent of the amended rule, the Department removed the words "the practice of storing and" from the phrase "to discontinue the practice of storing and releasing specimens" in the second paragraph of the preamble. The original sentence read, "The Department director has accepted a recommendation from the Congenital and Inherited Disorders Advisory Committee (CIDAC) to discontinue the practice of storing and releasing specimens for external research use without informed consent, and makes it the responsibility of the investigator of the proposed research to obtain informed consent from the parent or guardian for the release of the newborn's specimen."

Upon review of comments by the public and by legislators and after discussion with Department legal counsel, the Department made the following changes from the published Notice of Intended Action:

- Added an amendment to change the first-year storage temperature in 4.3(8)"a"(2) from "–70 degrees C" to "–75 to –80 degrees C."
- Added an amendment to 4.3(8)"c" to clarify that it is the responsibility of the researcher to obtain informed consent from the parents or guardians prior to the release of residual newborn screening specimens. The researcher can only ask for informed consent after approvals from the researcher's institutional review board (IRB), CIDAC and the Department. In addition, the Department added 4.3(8)"c"(4) to clarify the parental options for samples collected prior to these amendments. The Department did not rescind 4.3(8)"c"(3) as proposed under Notice.
- Added new 4.3(8)"f" to provide instructions for a parent or guardian who wants the child's residual newborn screening specimen returned to the parent or guardian or destroyed.
- Added an amendment to 4.3(9)"b"(3) to update the Web address of the CCID.

The changes required renumbering of some of the original Items from the Notice.

The State Board of Health adopted these amendments on January 11, 2017.

After analysis and review of this rule making, no impact to jobs has been found.

These amendments are intended to implement Iowa Code chapter 136A.

These amendments will become effective on March 8, 2017.

The following amendments are adopted.

ITEM 1. Rescind and reserve paragraph **4.3(2)"e."**

ITEM 2. Amend subparagraph **4.3(8)"a"(2)** as follows:

(2) The residual DBS specimen shall be stored for the first year at ~~−70~~ −75 to −80 degrees C.

ITEM 3. Amend subparagraph **4.3(8)"b"(4)** as follows:

(4) ~~A researcher for research purposes, under the terms and conditions provided in this rule.~~ A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

ITEM 4. Amend paragraph **4.3(8)"c"** as follows:

c. Research. A residual newborn screening specimen may be released for research purposes only if written consent has been received by the researcher from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) Investigators shall submit proposals to use residual newborn screening specimens to the center. Any intended use of the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.

(3) Research on ~~anonymized or identifiable~~ residual newborn screening specimens shall be allowed only in instances where research would further: newborn screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

(4) For specimens collected prior to January 1, 2016, a parent or guardian may send a letter stating that the newborn's specimen is not to be released for research purposes. This letter shall include the parent's or guardian's name, the newborn's name at birth, and the newborn's date of birth. The letter of notice shall be sent to the State Hygienic Laboratory at Newborn Screening Program, State Hygienic Laboratory, 2220 S. Ankeny Blvd., Ankeny, Iowa 50023-9093.

ITEM 5. Adopt the following **new** paragraph **4.3(8)"f"**:

f. Return or destruction of specimens. A parent or guardian may request return or destruction of the parent's or guardian's newborn's residual newborn screening specimen by contacting the executive officer of the center for congenital and inherited disorders by calling 1-800-383-3826, or by mail to Executive Officer, Center for Congenital and Inherited Disorders, Iowa Department of Public Health, 321 E. 12th Street, Lucas State Office Building, Des Moines, Iowa 50319-0075.

ITEM 6. Amend subparagraph **4.3(9)"b"(3)** as follows:

(3) Newborn CCHD screening shall be conducted by pulse oximetry or other means in accordance with the most recently published guidelines, algorithms, and protocols as outlined by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association, or subsequent guidance by the organizations listed in this subparagraph. Materials are available on the CCID Web page at ~~http://idph.state.ia.us/genetics/newborn_screening.asp~~ http://idph.iowa.gov/genetics/public/newborn-screening.

ITEM 7. Amend paragraph **4.3(9)"e"** as follows:

e. Reporting results of newborn CCHD screening. ~~At such time as the CCHD reporting system is implemented, results~~ Results of newborn CCHD screening shall be reported in a manner consistent with other newborn screening (formerly referenced as metabolic screening) reporting.

ITEM 8. Amend paragraph **4.3(10)"f"** as follows:

f. Upon department approval of proposed budgets, a portion of INSP and IMPSP fees shall be distributed to the department to support ~~the percent of effort of the executive officer of~~ activities of the INSP and the IMPSP at the center for congenital and inherited disorders (CCID).

ITEM 9. Amend rule 641—4.11(136A) as follows:

641—4.11(136A) Purpose. CIDAC represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and ~~congential~~ congenital disorders.

[Filed 1/11/17, effective 3/8/17]
[Published 2/1/17]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/1/17.